

international, except for activities carried out pursuant to treaties.

(c) This guidance does not preempt the agencies' authority and responsibility to make regulatory or procurement decisions authorized by statute or required to meet programmatic objectives and requirements. These decision-making activities include: determining the level of acceptable regulatory or procurement risk; setting the level of protection; balancing risk, cost and availability of technology (where statutes permit) in establishing regulatory and procurement objectives; and determining or implementing procurement or regulatory requirements necessary to meet programmatic or regulatory objectives. Each agency retains broad discretion in its selection and use of regulatory and procurement conformity assessment practices and may elect not to use or recognize alternative conformity assessment practices if the agency deems them to be inappropriate, inadequate, or inconsistent with statutory criteria or programmatic objectives and requirements. Nothing contained herein shall give any party any claim or cause of action against the Federal government or any agency thereof. Each agency remains responsible for representation of the agency's views on conformity assessment in matters under its jurisdiction. Each agency also remains the primary point of contact for information on the agency's regulatory and procurement conformity assessment actions.

#### § 287.2 Definitions.<sup>1</sup>

*Accreditation* means a procedure used to provide formal notice that a body or person is competent to carry out specific tasks. These tasks include: sam-

pling and testing; inspection; certification; and registration.<sup>2</sup>

*Agency* means any Executive Branch Department, independent commission, board, bureau, office, agency, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commission subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government.

*Agency Standards Executive* means an official designated by an agency as its representative on the Interagency Committee for Standards Policy (ICSP) and delegated the responsibility for agency implementation of OMB Circular A-119 and the guidance in this part.

*Certification* means a procedure used to provide written assurance that a product, process, service, or person's qualifications conforms to specified requirements.

*Conformity assessment* means any activity concerned with determining directly or indirectly that requirements are fulfilled. Requirements for products, services, systems, and organizations are those defined by law or regulation or by an agency in a procurement action. Conformity assessment includes: sampling and testing; inspection; supplier's declaration of conformity; certification; and quality and environmental management system assessment and registration. It also includes accreditation and recognition. Conformity assessment does not include mandatory administrative procedures (such as registration notification) for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions. Conformity assessment activities may be conducted by the supplier (first party) or by the buyer

<sup>1</sup>Definitions of accreditation, certification, conformity assessment, inspection, supplier's declaration of conformity, registration and testing are based on the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC), Guide 2 (1996). In certain industrial sectors, it is recognized that organizations other than ISO or IEC may issue definitions relevant to conformity assessment, such as the Codex Alimentarius Commission with respect to the food industry sector.

<sup>2</sup>For some agencies, accreditation may mean that a body or person meets requirements defined in a specific section(s) of the CFR. The referenced section(s) may include only limited requirements for demonstration of technical competency.

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(second party) either directly or by another party on the supplier's or buyer's behalf, or by a body not under the control or influence of either the buyer or the seller (third party).

*Inspection* is defined as the evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging of the conformity of a product, process or service to specified requirements.

*NIST* means the National Institute of Standards and Technology, an agency within the United States Department of Commerce.

*Recognition* means a procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include: the accreditation of testing laboratories and inspection, certification, and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

*Registration* means a procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance.

*Sampling* means the selection of one or more specimens of a product, process, or service for the purpose of evaluating the conformity of the product, process or service to specified requirements.

*Supplier's declaration of conformity* means a procedure by which a supplier gives written assurance that a product, process, service or organization conforms to specified requirements.

*Testing* means the action of carrying out one or more technical operations (tests) that determine one or more characteristics or performance of a given product, material, equipment, organism, person's qualifications, physical phenomenon, process, or service according to a specified technical procedure (test method).

### § 287.3 Responsibilities of the National Institute of Standards and Technology.

(a) Work with agencies through the Interagency Committee on Standards Policy (ICSP) to coordinate Federal,

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state and local conformity assessment activities with private sector conformity assessment activities. NIST chairs the ICSP; assists the ICSP in developing and publishing policies and guidance on conformity assessment related issues; collects and disseminates information on Federal, state and private sector conformity assessment activities; and increases public awareness of the importance of conformity assessment and nature and extent of national and international conformity assessment activities.

(b) Encourage participation in the ICSP by all affected agencies and ensure that all agency views on conformity assessment are considered.

(c) To the extent that resources are available, develop information on state conformity assessment practices; and, upon request by a state government agency, work with that state agency to reduce duplication and complexity in state conformity assessment activities.

(d) Review within three years from August 10, 2000, the effectiveness of the final guidance and recommend modifications to the Secretary as needed.

### § 287.4 Responsibilities of Federal agencies.

Each agency should:

(a) Implement the policies contained in the guidance in this part.

(b) Provide a rationale for its use of specified conformity assessment procedures and processes in rulemaking and procurement actions to the extent feasible. Further, when notice and comment rulemaking is otherwise required, each agency should provide the opportunity for public comment on the rationale for the agency's conformity assessment decision.

(c) Use the results of other governmental agency and private sector organization conformity assessment activities to enhance the safety and efficacy of proposed new conformity assessment requirements and measures. An example of this would be to collect and review information on similar activities conducted by other Federal, state and international organizations and agencies and private sector organizations to